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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|--------------------|-------------|-----------------------|------------------|
| 08/724,631 | 10/01/96 | MCCORMICK | M 700399.90053 |
| EXAMINER | | | |

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HM12/0528

| CLASS | PAPER NUMBER |
|-------|--------------|
| 1623 | 9 |

DATE MAILED: 05/28/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on amendment A

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-24 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

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PTOL-328 (Rev. 9/96)

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Applicant's amendment B filed 2-23-99 has been received and entered into the record.

Claims 1 - 24 are pending in the case. Claims 8, 13, and 18 have been amended by amendment B.

All 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

35 USC 112, Second Paragraph Rejection Withdrawn

The rejection of claims 8 and 13 - 24 under 35 USC 112, second paragraph, has been withdrawn in view of applicant's amendment to claims 8, 13, and 18.

35 USC 102(a) Rejection Withdrawn

The rejection of claims 1 - 5, 7, and 8 under 35 USC 102(a) as being anticipated by Hengen has been withdrawn because applicant has perfected his claim to priority under 35 USC 119(e) to provisional application number 60/004,668, filed October 2, 1995.

35 USC 103 Rejection Withdrawn

The rejection of claims 6 and 9 - 24 under 35 USC 103 as being unpatentable over Hengen in view of Arbige et al. or Burrows et al. or Stephens has also been withdrawn because applicant has perfected his claim to priority under 35 USC 119(e) to provisional application number 60/004,668, filed October 2, 1995.

New 35 USC 103 Rejection

Claims 1 - 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaillard et al. (Nucl. Acids Res. 18: 378, 1990) in view of Arbige et al. (4,927,644) or Burrows et al.

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(4,435,429). Claims 1 - 12 are directed to a method for precipitating nucleic acids comprising adding as a carrier, a polymer with a reporter molecule covalently attached, along with the standard alcohol and salts needed for precipitation. Claim 3 requires that the reporter molecule be attached through vicinal hydroxyl groups on the carrier molecule. Claim 4 requires the carrier to be a polysaccharide. Claim 5 limits the polysaccharide to glycogen. Claim 6 limits the polysaccharide to Type III glycogen. Claim 7 requires the reporter to be a dye or fluorophore. Claim 8 requires the linkage between the reporter and carrier be an amine linkage. Claims 9 - 10 specifies the exact structure of the dye. Claim 11 requires that the reporter be pH responsive. Claim 12 defines the exact structures of the pH responsive reporter molecules. Claim 13 - 24 are directed to the compositions used in the above nucleic acid precipitations comprising the carrier with a reporter covalently attached, alcohol, and salt. Claim 14 specifies the carrier to be a polysaccharide. Claim 15 requires the carrier to be a glycogen. Claim 16 requires the carrier to be Type III glycogen. Claim 17 requires the report to be a dye or fluorophore. Claim 18 requires that the carrier be attached to the reporter molecule via an amine linkages. Claims 19 - 21 specifies the exact structure of the reporter molecules. Claim 22 requires the reporter to be a pH responsive molecule. Claim 23 defines the exact structure of the pH responsive reporter molecules. Claim 24 further comprises a nucleic acid to be precipitated.

Gaillard et al. teaches that a polysaccharide (glycogen) can be used as an effective coprecipitant (i.e., carrier) molecule. See Figure 1, third lane in gel. Gaillard et al. does not teach the use of a polysaccharide coprecipitant with a reporter molecule covalently attached.

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However, Arbige et al. (4,927,644) does disclose a glucose polysaccharide with a reporter dye covalently attached (columns 6 - 7, Table 3): starch azure and amylose azure. Note that starch is a general term for animal glycogen. The starch azure and amylose azure are each used to detect the presence of alpha-amylase.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time of the invention to have modified the teaching of Gaillard et al. (that glycogen is an effective polysaccharide carrier for precipitating nucleic acids) by substituting the colored glycogen (starch azure) taught by Arbige for the art recognized benefit of being able to visibly follow the precipitation of small amounts of nucleic acids. Similarly, the compositions comprising the colored polysaccharide carrier, alcohol, and salt needed in the above method would have also been obvious to the person of ordinary skill in the art because the alcohol and salt are simply the routine components for any effective nucleic acid precipitation. Thus, the invention is prima facie obvious in the absence of clear and convincing evidence to the contrary.

The substitution of different types of glycogen or polysaccharides for the starch used in starch azure would have been routine and would have been expected to yield a product with comparable carrier properties. The artisan would have also found it obvious to have substituted any traditional dye or fluorophores for the azure blue of the starch blue with the expectation of obtaining a visible/fluorescent carrier with comparable precipitating properties. Finally, the coupling of the reporter molecule to the polysaccharide carrier by periodate oxidation followed by Schiff's base formation with the dye and then reduction with a borohydride would have also been

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obvious because this chemistry is the most convenient and widely used technique for binding any amino containing moiety to a polysaccharide.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Gary L. Kunz
GARY L. KUNZ
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GROUP 1200